GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:372
ANSWERED ON:20.11.2002
INFLOW OF BANNED DRUGS
KAILASH MEGHWAL;SURESH CHANDEL

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government are aware that the fatal medicines are being sold by the multi-national companies in India which are banned in other countries;

(b) if so, the details thereof;

(c) whether the Government have approved cent percent foreign investment in the drug sector and removed the condition of obtaining licence for selling up of units for production of drugs in the country by foreign companies;

(d) if so, the details thereof; and

(e) the steps taken/proposed to be taken in this regard?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a)&(b): No, Sir. There are no reports about fatal medicines being sold by the multinational companies in India which are banned in other countries. However, certain drugs and formulations banned in some countries at time continue to be marketed in other countries because the decision to do so is normally based on risk assessment process which is influenced by a number of factors such as the disease pattern in a country, the varying reactions of certain ethnic groups in a given population to the drug and the availability of safer substitutes as well as the cost factor involved in the treatment of a particular disease. There is also the overall awareness that administration of any drug is not absolutely free from side effects or adverse reactions in a statistically insignificant minority of the population.

The risk assessment of an approved drug begins with information about its review, restriction, discontinuation or ban in any country. The evaluation of the data is done in consultation with leading experts in the given specialization. Based on their advice, the matter is placed before the Drug Technical Advisory Board (DTAB), a statutory body which comprises of representativesfrom the medical profession, the State Drug enforcement authorities, experts institutions agencies that advise Government on technical issues related to the implementations of the Drugs and Cosmetic Act, 1940, like whether or not to ban/phase out an existing drug.

Out of 46 drugs previously reported by the WHO as banned in some countries, 26 drugs were never marketed in this country, of the remaining 20 drugs, 13 drugs have been discontinued based on expert evaluation and recommendation of the DTAB. While 7 drugs have been allowed to be continued to be marketed subject to cautionary statement and contra-indications being given on the label and in some cases on the package insert.

(c)to(e):The Pharmaceutical Policy - 2002 provides that foreign investment upto 100% will be permitted, subject to stipulations laid down from time to time in the Industrial Policy, through the automatic route in the case of all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations except in the case of bulk drugs produced by the use of recombinant DNA technology, bulk drugs requiring in-vivo use of nucleic acids as the active principles and specific cell/tissue targeted formulations.